

# Realising the Potential for Formulation in the UK

Final Report of the Formulation Special Interest Group Sponsored by the Technology Strategy Board June 2013 Special Interest Group

Formulation

# **EXECUTIVE SUMMARY**

Complex formulated products such as pharmaceutical tablets, cosmetic creams and gels, detergent powders, processed foods, paints, adhesives, lubricants and pesticides are ubiquitous in everyday life.

The design and manufacture of formulated products is a highly significant value-adding step, with a value multiplier ranging from around 3 – 100. This value translates to sales of formulated products by UK companies of around £180bn per year. There is an emerging overseas market of around £1000bn.

Formulating markets are growing strongly. Drivers for this arowth include:

- Globalisation of production and branding and growth of open innovation business models.
- Increasing demand in the world's emerging economies.
- A growing awareness of sustainability; and a demand for natural / green / risk-free products.
- A growing population with a demand for personalised medicine and improved nutrition.

The UK has a strong, globally competitive advantage in formulation. Within the UK there are many significant centres for the industrial manufacture and R&D of formulated products. These include major centres for laundry detergents (P&G), personal care products (Unilever), agrochemicals (Syngenta), food (Nestle), coatings (AkzoNobel) and pharmaceuticals (AstraZeneca, GSK, Pfizer).

In addition to these companies, the supply chain for precursors, ingredients and enabling capabilities is well represented in the UK, with companies such as Croda, Innospec and Rockwood all having a major UK presence.

The UK also has a broad and thriving community of smaller companies, from specialist formulators through to providers of novel ingredients, instrumentation, process technologies and software who all provide products and services to the larger companies. Many of these are SMEs with origins in spinouts from the UK's universities, an indicator that the UK's industrial base in formulation is also supported by world-class academic expertise.

A shift to a more scientific or 'data-driven' formulation approach is needed to exploit growing global demand for differentiated products with novel effects, delivered quickly and sustainably. Established capability and incremental development are approaching their limits. This 'data-driven design' shift is happening, but very slowly and piecemeal in the UK. Technically, all of the pieces of the jigsaw already exist but not within any one organisation. They are widely dispersed and to bring them together requires a complex convergence of capabilities and organisations. There is however a growing desire within the UK to collaborate and share best practice, ideas and knowledge across industry borders. Companies from different formulating industries which do not compete with each other want to collaborate to tackle common technical challenges and opportunities, and despite the diversity in end-use applications, the level of cross-over potential in formulation is particularly high as seemingly unrelated products often share very complex microstructures.

Building on the opportunity described above, this report details the findings of the Technology Strategy Board's (TSB) Formulation Special Interest Group (SIG) which includes a detailed analysis of current UK capabilities, opportunities for cross-sector collaboration and recommendations for intervention from the TSB (and others). Specifically, the main interventions proposed and scoped in this report are i) a portfolio of collaborative R&D projects and a ii) an Open-access Formulation Innovation Centre. The centre, developed in partnership with industry, has been identified as the most appropriate mechanism to drive innovation and enable the UK to be in a position to lead the world in this step change in formulated product design and manufacture.



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# FORMULATION AND ITS IMPORTANCE TO THE UK

# Global Markets for Formulated Products and Drivers for Change

Complex formulated products such as pharmaceutical tablets and suspensions, cosmetic creams and gels, detergent powders, processed foods, paints, adhesives, lubricants and pesticide suspensions are ubiquitous in everyday and industrial life.

An overview of the main global industries, companies and product types which generate value from formulated products and the exploitation of formulation science and technology is given in Box 1.

Formulation science and technology provides companies with tools to meet the challenges and benefit from the opportunities of those industries. Previous roadmapping and foresighting work has indicated a number of megatrends and drivers which are having an impact in the formulating industries for instance:

- Societal drivers towards better water and air quality; a growing awareness of sustainability; and a demand for natural / green / risk-free products.
- A growing middle class of consumers in developing countries demanding pharmaceutical, food and cosmetic products with the variety, quality and performance of developed world products.
- An ageing population with a demand for cosmetic products, regenerative and personalised medicine as well as improved nutrition.
- Growing needs for fast, flexible and locally distributed manufacture; modular plant design; in-line measurement and intelligent process control.
- Increasing technological opportunities from renewable and sustainable feedstocks; demands for lower water / CO2 / waste processes as well as reduction, remanufacture, re-use and recycling in product design.
- Globalisation of production and branding and growth of open innovation business models.
- Growth in regulatory control of industries and introduction of product registrations schemes.

## The Strengths of the UK in Formulation

The design and manufacture of formulated products is a highly significant value-adding step, with a value multiplier ranging from around three to over one hundred when the market value of a formulated product is compared with the value of its ingredients. This value adds up to a market value in the UK alone for formulated products of around £180 billion per year and there is a potential in emerging overseas markets of around £1,000 billion (Source: Chemistry Innovation KTN Strategy Report 2010). Such markets are growing strongly for reasons such as industrialisation and the demands of a growing middle-class consumer base for high quality cosmetics and pharmaceuticals. In addition it is estimated that there is an additional market in associated upstream supply chain materials and enabling capabilities (such as ingredients, process technology equipment, laboratory equipment, services and consultancy) of a similar magnitude to the market for formulated products themselves.

The combined formulating industries contribute a significant surplus to the UK balance of trade figures and represent about 30% of total UK manufacturing employing about 1.5 million people. Around 25% of these employees are educated to at least tertiary level. The 2010 UK R&D Scoreboard (Source: BIS) shows that of the top 1000 UK R&D spenders, 222 companies appear in relevant industries. These 222 companies spent a total of nearly £10.5 billion in 2009 on R&D (in formulation as well as other areas) at an average of 6% on sales – which may be in UK or export. A similar analysis of the top 1000 global R&D spenders from the same source indicates that 227 companies appear in the relevant industries, spending £90 billion on R&D.

Within the UK there are many significant centres for the industrial manufacture and R&D of formulated products. In many cases these centres are parts of large multinational companies and are therefore global in their impact and influence, contributing to UK export performance in products and services as well as to growth and employment in the UK. These centres range across the full set of formulating industries and include major centres for laundry detergents at P&G in Newcastle, for personal care products at Unilever in Port Sunlight, for agrochemicals at Syngenta in Berkshire, for coatings at AkzoNobel in the North East and in Slough and for pharmaceuticals at AstraZeneca in Macclesfield.

In addition to the formulating companies the supply chain is well represented in the UK, with ingredients companies such as Croda, Innospec and Rockwood and instrumentation companies such as Malvern Instruments all having a major UK presence. A picture of the breadth and depth of UK industrial investment in Formulation is shown in Box 2.

### Box 1 - Overview of Formulation in Industry Worldwide

| Industry   | Formulating Co<br>(examples)                        | ompanies   | Product Types and Applications (examples)   |
|--|---|--|---|
| Pharmaceuticals<br>and healthcare                | Pfizer<br>AstraZeneca<br>Novartis<br>GSK<br>J&J     | Merck<br>Lilly<br>Bayer<br>Reckitt Benckiser<br>Bristol-Myers Squibb | <ul> <li>Oral dose tablets</li> <li>Suspensions</li> <li>Capsules</li> <li>Controlled release microcapsules</li> <li>Injectable (parenteral) formulations</li> <li>Inhalable formulations</li> </ul>  |
| Cosmetics and<br>personal care                   | P&G<br>Unilever<br>L'Oreal<br>Boots<br>Beiersdorf   | Henkel / Schwarzkopf<br>GSK<br>J&J<br>Shiseido<br>Estee Lauder       | <ul> <li>Shower gels and shampoos</li> <li>Lotions and creams for skin care</li> <li>Deodorant sprays</li> <li>Hair colour foams</li> <li>Make-up sticks and gels</li> <li>Toothpaste and mouthwash</li> </ul>                                    |
| Household and<br>professional care               | P&G<br>Unilever<br>Henkel<br>Reckitt Benckiser      | SC Johnson<br>Ecolab<br>Diversey<br>McBride                          | <ul> <li>Laundry detergent powders and liquids</li> <li>Fabric conditioner liquids</li> <li>Domestic and professional surface</li> <li>cleaners, disinfectants, polishes</li> <li>Air care sticks and sprays</li> </ul>                           |
| Agrochemicals                                    | Syngenta<br>Bayer<br>Monsanto                       | BASF<br>Dow<br>Dupont  | <ul> <li>Water-dispersible extruded granules</li> <li>Suspension concentrates</li> <li>Self emulsifiable concentrates</li> <li>Seed coatings</li> </ul>   |
| Paints and coatings                              | PPG<br>Sherwin Williams<br>AkzoNobel                | Dupont<br>BASF<br>Dow  | <ul> <li>Water and solvent based decorative paints</li> <li>Water and solvent based automotive paints</li> <li>Powder coatings</li> <li>Anticorrosion, antifouling, anti-drag coatings</li> <li>Varnishes, stains</li> </ul>                      |
| Adhesives, sealants and<br>construction products | Henkel<br>Bostik<br>AkzoNobel<br>3M                 | BASF<br>HB Fuller<br>Dow Corning<br>Ashland                          | <ul> <li>Water or solvent based sealants, grouts, caulks</li> <li>Speciality adhesives for industry</li> <li>Adhesives for domestic use</li> </ul>  |
| Formulated foods and beverages                   | Nestle<br>Kraft<br>Mondelez                         | Unilever<br>Pepsico<br>Cargill                                       | <ul> <li>Sauces, mayonnaise, dips</li> <li>Dairy products and spreads</li> <li>Ice cream and desserts</li> <li>Bakery products</li> <li>Chocolate and confectionary</li> </ul>  |
| Inks and dyes                                    | Sun Chemical<br>Flint<br>Huntsman<br>Canon<br>Epson | Domino<br>Hewlett Packard<br>Dystar<br>FUJIFILM Imaging Colorants    | <ul> <li>Printing inks (water and solvent based)</li> <li>for reprographics and packaging</li> <li>Digital ink-jet inks and toners</li> <li>Printed electronics and displays</li> <li>Textile and leather colorants</li> </ul>                    |
| Lubricants, cutting fluids and fuel additives    | Exxon Mobil<br>Shell<br>BP Castrol                  | Fuchs<br>Infineum<br>Innospec  | <ul> <li>Engine lubricants</li> <li>Industrial lubricants</li> <li>Self emulsifiable metal-working fluids</li> <li>Fuel additive packages</li> </ul>  |
| Process chemical<br>formulations                 | Nalco<br>GE<br>Johnson Matthey<br>Kemira            | Ashland<br>Haliburton<br>Schlumberger<br>Clariant                    | <ul> <li>Biocides and descalants for water treatment and paper production</li> <li>Solid-state catalysts</li> <li>Enhanced Oil Recovery emulsions for oil production</li> <li>Fracking fluids</li> <li>Demulsifiers for oil production</li> </ul> |

Box 2 - Examples of Major UK Industrial Centres in Formulation and the Supply Chain

| Industry                                      | Companies (examples)   | Location and Function  |
|---|--|--|
| Pharmaceuticals<br>and healthcare             | Pfizer<br>AstraZeneca<br>MSD (Merck)<br>GSK<br>Reckitt Benckiser<br>Bristol-Myers Squibb | Formulation development – Kent<br>Formulation development and manufacture –<br>Cheshire<br>Formulation development – Hertfordshire<br>Formulation development and manufacture –<br>Hertfordshire<br>Formulation R&D and manufacture – Humber<br>Formulation R&D - Wirral |
| Cosmetics and personal care                   | P&G<br>Unilever<br>GSK   | R&D and Manufacturing – S.E. England<br>R&D and Manufacturing – Wirral<br>R&D and Manufacturing – S.E. England   |
| Household and professional care               | P&G<br>Unilever<br>Reckitt Benckiser   | R&D – Laundry Detergents – Newcastle<br>R&D – Household Products – Wirral<br>R&D and Manufacturing - Humber  |
| Agrochemicals                                 | Syngenta   | Formulation R&D – Berkshire  |
| Paints and coatings                           | AkzoNobel<br>BASF  | R&D and Manufacturing – Decorative and<br>Industrial Coatings – S.E. and N.E. England<br>Industrial Coatings Manufacture – N.W.<br>England   |
| Adhesives, sealants and construction products | Henkel<br>Bostik   | R&D – Adhesives – S.E. England<br>Development – UK   |
| Formulated foods and beverages                | Nestle<br>Mondelez (Cadbury)<br>Unilever   | R&D and Manufacturing – York<br>R&D and Manufacturing – Reading,<br>Birmingham<br>R&D – Bedfordshire   |
| Inks and dyes                                 | Fujifilm   | R&D Inkjet Colorants – Manchester and Scotland   |
| Fuel additives                                | Infineum   | R&D - Oxfordshire  |
| Ingredients for Formulations                  | Croda<br>Innospec  | R&D and Manufacturing – Humber and N.W.<br>England<br>R&D and Manufacturing - Wirral   |

As well as the major multinationals, the UK plays host to a broad and thriving range of smaller companies, from smaller specialist formulators through to providers of novel technologies, ingredients, measurement instrumentation, laboratory automation, modelling software and R&D services. Some examples of successful and emergent SMEs engaged in the formulation supply chain are described in the case studies in Box 3.

### Box 3

Examples of some UK SMEs Engaged in the Formulation Supply Chain

### Revolymer

SME spinout from University of Bristol Source: www.revolymer.com

Revolymer is a technology company that designs, develops and formulates novel polymers to improve the performance of existing consumer products within the fast moving consumer goods (FMCG) and other industrial markets. Revolymer aims to generate significant and growing high quality revenue streams by licensing its unique technologies to manufacturers and marketers within these markets. Potential applications for the business's technologies are in the household products, personal care and coatings & adhesives product areas and in medicated chewing gum (including nicotine gum) and confectionery chewing gum.

### **Promethean Particles**

SME spinout from University of Nottingham Source www.prometheanparticles.co.uk

Promethean Particles designs, develops and manufactures inorganic nanoparticle dispersions to the customer's specifications. The company uses continuous hydrothermal synthesis to make the optimum product for each application and backs this up with large scale manufacturing capability (currently up to 10 tons per year with a 100 TPA plant build underway). Promethean Particles provides a bespoke service to a range of industrial partners and works with its customers to develop the material they need. Every application of nanoparticles is unique and requires a tailor-made material to achieve optimum results.

# Byotrol

SME founded following technology invention in a family paint company Source www.byotrol.co.uk

The Byotrol core technology was invented in the late 1990's to help a bakery improve its microbe control. The results were exceptional so Byotrol started on a rigorous process to ensure that the technology was tested, proven and developed to bring this same solution to any business or consumer hygiene need or concern. It is now approved safe for use in the high need hygiene environments of healthcare, food production, animal welfare and many other environments including the home. Byotrol works with brand leaders across the globe to ensure everyone has access to this technology. Now products using Byotrol are on sale for consumers and extensively used in industry in Europe, Asia, the America's and Africa.



Many of these SMEs have their origins in spinouts from the UK's universities and this is an indicator that the UK's industrial base in formulation is supported by world-class academic expertise, including in colloid science, surfactants, particle design, nanotechnology, particle processing, materials science, measurement, high-throughput automation and computational methods for modelling and simulation. The multidisciplinary nature of formulation is also indicated by the spread of academic departments and faculties represented, which range from chemistry and chemical engineering through to physics, materials science and pharmacy.

One consequence of the multidisciplinary nature of formulation is that individual groups rarely refer to formulation as a whole, concentrating instead on specific scientific themes. A result of this fragmented academic approach is a lack of a "big picture" for formulation in the UK. Examples of UK academic activities in scientific themes relevant to formulation are given in Box 4.

#### Box 4

# Examples of UK Academic Centres Relevant to Industrial Formulation

# University of Hull – Surfactants and Colloid Chemistry

The research of the Surfactant & Colloid Group is concerned with the surface and colloid chemistry of a wide range of systems including monolayers, micelles, vesicles, polymers, microemulsions, foams, emulsions, particles in surfaces and colloidal dispersions. Established since 1986, the group comprises a total of over 30 researchers including 7 academic staff members and has a strong reputation for fundamental research in areas closely linked to technological applications, pursued in collaboration with a wide network of industrial partners.

# University of Birmingham – Formulation Engineering

In 2001, the Centre for Formulation Engineering was created to address a growing demand for a process engineering paradigm concerned with the production of formulated materials. The research issues addressed at Birmingham affect widely different industry sectors but have common threads: the need is to understand the processing that results in optimal nano- to microstructure and thus optimal effect; products are either structured solids, soft solids or structured liquids, with properties that are highly process-dependent; and for optimal performance the process must be designed concurrently with the product, as to extract commercial value requires reliable and rapid scale-up.

# University of Liverpool - High-throughput Technologies

The Centre for Materials Discovery (CMD) at Liverpool has established a core capability in High Throughput (HT) techniques and instrumentation to enable the discovery of innovative materials for high value applications. In a recent TSB project, CMD's expertise in HT technology was used to explore a wide range of formulation conditions and compositions incorporating oxidised cellulose as a sustainable thickening agent for personal care products. Robotic formulation platforms were employed to efficiently screen component interactions in model systems and to produce arrays of full formulations to optimise lead compositions. Using this approach, over 300 model formulations per week could be screened, covering a wide range of experimental factors in far greater detail than could be managed using traditional bench-top techniques.



With industrial and academic bases in formulation which are both broad and deep, the strategic importance of formulation to the UK economy was recognised by the Technology Strategy Board in its High Value Manufacturing Strategy 2012-2015. This strategy, which is intended to guide public and private investment in manufacturing technology, explicitly names 'understanding, manufacturing and designing formulated products' as one of 22 strategic national competencies. Furthermore formulation supports an additional 14 of those competencies.

The UK is not alone in recognising the importance of formulation. In the USA for instance, a National Formulation Science Laboratory opened recently, supported by federal and industrial funding and run through the University of Southern Mississippi. The TSB-funded 2011 Formulation Mission from the UK run by Chemistry Innovation KTN

### Formulation - the Market Opportunity for UK Industry

The industry trends and drivers described earlier open up significant commercial opportunities for better exploitation of formulation science and technology, these include:

- Fuel formulation for increased energy efficient fuels.
- Lubricant formulation for reduced friction.
- Adhesive and sealant formulation to support more flexible and lower cost manufacturing.
- New dosage forms of medicines for product line extension and improved performance.
- Formulation to improve solubility and bioavailability of new and old pharmaceutical APIs.
- Processing methods to reduce waste and quality costs in pharmaceutical manufacturing.
- Improved functionality and better targeting of product in cosmetics and home care.
- Improved storage stability for reduced complaint costs in all industries.



- More flexible production and more rapid formulation development in all industries.
- New food formulation for improved microstructure to give desired feel, taste and performance while reducing fat, sugar and salt levels.
- Controlled release of food ingredients to allow improved cost-performance.
- Enabling of new nanotechnologies to provide coatings with improved functionality.
- More precise control of rheological performance in coatings application to provide better functionality.
- Formulation of process chemicals to enable better yield and reduced down-time in e.g. oil, minerals and paper production.
- Wider use of raw materials from sustainable sources.





# Formulation – The Challenge of Technical Complexity and Use of Science

Exploitation of these opportunities brings challenges however. Far from being just simple mixtures of chemical ingredients, formulated products are in fact the end result of a concerted design process which must take into account the complexity of the ingredient set; the influence of multiple phases and product microstructure as well as a potentially conflicting set of performance, economic and environmental parameters. In addition to the task of product design, formulating companies are also presented with challenges in the area of process design and manufacturing.

Despite the high levels of expertise, understanding and commercial success associated with formulation in the UK, many industry practitioners have long expressed the need for a more coordinated - as well as a more scientific - approach

# Formulation - The Opportunity to Collaborate and Share Best Practice Across Sectors

Furthermore, there is a great opportunity to co-operate and share best practice, ideas and knowledge across industry borders. Companies from different industries which do not compete with each other are now seeing this chance to collaborate to tackle common challenges and opportunities. Despite the diversity in end-use applications, many companies are faced with common technical challenges. This is because formulated products which may be externally distinct in fact often share very complex microstructures. It is these microstructures and physical interactions as much as the chemistry of the ingredients may determine the product properties and performance of a formulated product. A further symptom of the historic fragmentation of formulation by industry and by academic discipline has been a patchy provision of skills and training in formulation. This topic is dealt with in more detail in a later section, but clearly the lack of suitable skills amongst the UK's formulation R&D practitioners could potentially leave industry less able to respond to opportunities to innovate in formulation. Over the last few years, the need to address all the issues identified above, as well as to realise the opportunities arising from formulation has been evident as part of a number





to the exploitation of formulation science and technology. The view has been expressed that the ability of industry to harness an understanding of complex formulation behaviour through R&D, scale up, manufacturing, distribution and use is immature. Historically companies have concentrated their R&D efforts on synthesising novel molecules, with less attention being paid to formulation. Under time pressure to deliver new products companies often rely on trial-anderror approaches rather than try to gain a more fundamental understanding of their systems. With diminishing returns for novel substance R&D, focus is now being applied on the opportunities to deliver value from formulation product and process development.

- significant activities, initiatives and position statements (which all had significant industry input) including: Royal Society of Chemistry: "Chemistry for Tomorrow's World: A roadmap for the chemical sciences" (2009)
- IChemE: Formulated Product Engineering, Special Interest Group (2009)
- Intelligent Formulation Network: Roadmapping and Foresighting Exercise (2009-2010)
- Chemistry Innovation KTN: Strategy Report (2010)
- Chemistry Innovation KTN: Formulation Mission to USA (2011)
- Chemistry Innovation KTN: Annual Report (2010-2011)
- Intelligent Formulation Network: Proposal for a Formulation Centre (2011)
- Institute for Manufacturing: "A landscape for the future of high value manufacturing in the UK" (2012)



# THE FORMULATION SPECIAL INTEREST GROUP AND ITS REMIT

Following the launch in 2012 of its strategy for High Value Manufacturing, the Technology Strategy Board asked Chemistry Innovation KTN to set up a Special Interest Group (SIG) for Formulation, to be chaired and guided by industry in order to advise on future public co-investment in innovation in formulation.

The Formulation SIG was provided with strong engagement and guidance via companies represented on an Industry Leadership Group which was chaired by Graeme Armstrong of AkzoNobel. The Formulation SIG was thus able to engage with a wide range of companies across the UK's formulating industries (Box 5). Other stakeholders such as IChemE, Royal Society of Chemistry, Academy of Pharmaceutical Sciences, British Association of Chemical Specialities, Cogent Sector Skills Council and the Technology Strategy Board were consulted during the period of the SIG. The Formulation SIG was managed by Chemistry Innovation with support from other organisations (Box 6).

As a considerable amount of consultation and opinionforming had already been undertaken in the formulation area, the SIG did not need to cover old ground. In response to expressed industry demand, Chemistry Innovation KTN announced in its annual report in 2011 that the establishment of "a centre in science-based formulation that will increase penetration in global markets for UK based companies" would become one of its top ten deliverables. Therefore, instead the approach was taken to summarise and build on this earlier work and then guide and advise on future activities by providing clear conclusions and recommendations. The Formulation SIG was therefore a deliberately time-limited activity and ran between July 2012 and March 2013.

The remit of the Formulation SIG was to deliver:

1. A full proposal for a national formulation centre.

2. A national formulation centre business plan and industryled project consortium.

3. A critical mass of key stakeholders, particularly an industry leadership group, which buys into and owns an overarching national 'Action Plan for UK Formulation'.

4. A suite of potential collaborative R&D projects/consortia and an associated project building programme/offering translatable into the national centre.

5. A final SIG report with recommendations for follow-on activity.

In practice the SIG also encompassed several additional related areas, in particular advising the Technology Strategy Board on a collaborative R&D competition in formulation as well as co-ordinating and communicating relevant activities ongoing in skills and training for formulation. Both of these topics are therefore covered in this report.

#### Box 5 Examples of Companies Consulted during the Formulation SIG

Afton Chemical AkzoNobel Astech Projects AstraZeneca Bristol Myers-Squibb Chemspeed Croda BP Britest FUJIFILM Imaging Colorants Givaudan GSK Harman Technology Innospec Johnson Matthey Lonza Merck Novidec Oxford Advanced Surfaces Pfizer Procter & Gamble Reckitt Benckiser Revolymer Schlumberger Syngenta Unilever

# Box 6

Formulation SIG Management Team

Darren Ragheb, Chemistry Innovation KTN

Colin Tattam, Chemistry Innovation KTN

Steve Fletcher, Chemistry Innovation KTN

Hilda Coulsey, HAC Consultancy/IChemE

Graham Hillier, Centre for Process Innovation

Jim Bullock, iFormulate Ltd



# **BUILDING PROJECTS AND** COLLABORATION IN FORMULATION

The project building activity of the formulation SIG served two • In the context of collaborative project building/delivery, main aims:

1. To build a strategic portfolio and framework for collaborative projects, primarily for delivery via the proposed Formulation Centre.

2. To facilitate the creation of a broader base of collaborative projects and consortia, mainly for delivery via a forthcoming TSB collaborative R&D competition

Whilst the following sub-sections provide more detail on the outputs against these aims, the high-level learning and conclusions taken from this exercise are:

- Feedback and active participation in the project building activities validated the premise that there is a need and appetite for collaboration, particularly cross-sector and multidisciplinary, in formulation.
- There is an associated demand from the formulation community for established TSB collaboration support mechanisms - in particular, KTN networks/project building, collaborative R&D/feasibility competitions.

feedback is clear that there is a need for a Formulation Catapult centre.

to enable collaborative projects that don't fit the mould against other TSB tools - e.g. infrastructural, enabling platform technologies, short-term projects.

To deliver added value knowledge-transfer activities e.g. 'communities of practice' to trigger future project activities; access/signposting to an extended national network.

• This component of the SIG activity demonstrated the value added in using dedicated expert resource and structured engagement mechanisms to build and stimulate the community and associated project activity. The TSB should work with the KTNs, the HVM Catapult and other relevant networks e.g. IChemE, RSC, to ensure this continues.

#### A strategic portfolio and framework for collaborative projects

The objective of this activity was to build a strategic portfolio of technical themes and project clusters to include in the business plan and to direct future activities of the proposed Formulation Centre. This output in turn will stimulate the engagement and commitment of potential member companies and enables the initial planning of the resources, expertise and facilities required for the Centre.

The strategic project portfolio will thus not only guide the activities and projects of the proposed Formulation Centre but also form the basis for, and stimulate, further and broader activities in the UK's extended formulation community of companies, universities and other institutions.

Following industry consultation and a series of workshops (summarised later in this section) a strategic collaborative project portfolio has been drawn up. This proposed portfolio (summarised in Box 7) is aligned to the five themes for formulation (Radical Formulated Product Design; Formulation for Delivery; Radical Formulation Process Design; Formulation for Stability and Formulation for Sustainability). Some duplication of ideas between the five themes is inevitable but under each several sub-themes/project clusters (typically up to around £2m per project over a 2-5 year timescale) and longer-term aspirational Grand Challenges (10 year or longer timescale, £10m+ programmes) have

been defined. At the conclusion of the SIG, eight project sub-themes were chosen by Industry Leadership Group companies as being of highest priority/interest and best delivered via a national formulation centre.

The work presented here on strategic project (sub)themes has been used to inform the Formulation Centre business plan by enabling an initial estimate of the Centre investment plan as well as by focusing and validating expertise, facilities and partners identified for inclusion in the Centre business plan.

The strategic lead organisations in the proposed Formulation Centre (which will mainly be first-mover Tier 1 member companies, with Tier 2 and others as appropriate) as well as the partner spokes will work to prioritise and further refine the sub-themes in the strategic framework and formalise collaborations over the coming months ready for the start-up of the Formulation Centre (from April 2014).

It is anticipated that these projects will be funded via a combination of catapult core funding, TSB Collaborative R&D competitions, EU projects and a variety of matched options. Additionally individual company contract research projects will take place, which should generally align with the project themes

# Box 7

### Strategic Innovation Portfolio for the Formulation Centre

Project themes marked with \* were those chosen as the top eight project sub-themes by SIG Industry Leadership Group companies as being of highest priority and most interest to those companies.

# 1. Radical Formulation Process Design

## Grand Challenge:

Engineering distributed supply chains, optimised for cost and sustainability with reduced cost of quality and increased consistency.

### **Priority Project Sub-Themes:**

P 1\*: Prediction at scale - used fundamental understanding, measurement and design to predict scale-up and scale down. Produce scalable process technology for formulation manufacturing using distributed supply chains.

P 2: Manufacturing and operability for quality and cost using models for optimised waste, cost, robustness and quality. Building QBD approaches by predicting ease of formulation and manufacturability.

P 3\*: Switching from batch to continuous processing for more flexible manufacturing.

P 4: Establishing demonstrator units for new manufacturing and measurement technologies.

# 2. Formulation for Delivery

### Grand Challenge:

Enabling or improving precisely controlled and targeted use of ingredients or providing radically new formulation architecture or product microstructure. The Grand Challenge might be sector specific, e.g. "Design a Tablet".

### **Priority Project Sub-Themes:**

D 1: Improving product effects and developing new product effects (e.g. component lifetime in engines, detergents that function at lower temperature and water use, foods with reduced salt, sugar or fat, enhanced bioavailability of APIs).

D 2\*: Projects to develop new product forms (e.g. formulation for personalised medicine, controlled and targeted release formulations, encapsulation, enabling of nanotechnologies for improved functionality).

# 3. Radical Formulated Product Design

# **Grand Challenge:**

Developing new products to meet individual needs, specifically targeted, guickly, with competitive advantage and via new IP. Developing ways to generate variety in a product portfolio to respond to different conditions; increasing flexibility in manufacturing.

# **Priority Project Sub-Themes:**

T 1\*: Use of high-throughput technologies to trial, test and model to aid development of new applications using fundamental scientific understanding of real product and process behaviours.

T 2:\* Enable better delivery of an active via a more (cost) effective product, e.g. multi-active combination products with multiple release profiles. Build complex microstructures to give predicted desired properties.

# 4. Formulation for Stability

# Grand Challenge:

Achieve full understanding of multi-component interactions and multi-phase behaviours of a product family. Be able to predict the effect of changing components or conditions during development, manufacture and use.

# **Priority Project Sub-Themes:**

St 1\*: Data handling, modelling and simulation to extend distance and time scales of modelling and prediction.

St 2\*: Control of (micro) structures - measurement & control for desired mechanical & stability properties across length scales

St 3\*: Understanding of chemical and physical stability of individual components (e.g. surfactant microstructures, biologic Active Pharmaceutical Ingredients (APIs), nanoparticles) to improve stability and quality of formulations.

# 5. Formulation for Sustainability

### Grand Challenge:

Complete redesign of a product and the processes in its whole supply chain for the minimum environmental impact.

### **Priority Project Sub-Themes:**

Su 1: Use of natural and sustainably sourced raw materials for effect.

Su 2: Customising and targeting the product for 100% product in use.

Su 3: Reduction of water in manufacture and use and replacement of volatile organic compounds (VOCs).

Su 4: Separation processes for complex mixtures for recover and re-use of components.

### **Communities of Practice**

During the project building activity the potential to build Communities of Practice (CoPs) delivered by Formulation Centre was recognised. CoPs would be responsible for transferring knowledge in the underpinning technical topics which cut across all five strategic project themes for the Centre. The CoPs would thus help to develop the Centre as a repository of cross-sector knowledge; would form a much wider resource and expertise base for Centre experts to call on and would form a foundation for initiating new projects. As an example CoPs could cover the following cross-cutting technical themes:

- Characterisation and measurement
- Modelling and data management
- Prototyping and trials
- Cross sector transfer of knowledge and solutions
- Solid formulations, liquid formulations
- High throughput experimental methods

To a certain extent, some CoPs already exist within KTNs and professional bodies (e.g. Royal Society of Chemistry, IChemE) in subjects such as particles, rheology and colloids. It will be important to ensure appropriate engagement with these groups to avoid duplication.

# Industry Consultation and Project Building Workshops:

Facilitating the creation of a broader base of collaborative projects

Previous work over recent years (summarised in the previous section of this report) had provided a number of background themes and topics as well as interested organisations that the SIG team wished to obtain an updated view from. In addition new potential lead organisations and smaller innovative companies were approached through the communications channels available to the SIG.

In addition to interviews with individuals in 20 companies representative of the overall UK Formulation community, four themed public workshops with a total of over 80 attendees were held between October 2012 and January 2013:

1. Stability: The understanding to control chemical and physical mechanisms, time and scale to precisely deliver what, to where, by when.

2. Closing the loop: Data-rich formulated product and process design.

3. Sustainability: Designing formulations for a more sustainable future.

4. Process: Process design and manufacture of formulated products.

In each of these workshops several projects were developed by participants and these are summarised in Box 8.



### Box 8

# Project Building Workshops and Projects developed

**1. Stability:** Using understanding to control chemical and physical mechanisms, time and scale to precisely deliver what, to where, by when.

- Improved, integrated data handling, experimentation, prediction and modelling systems to enable stability control over distance and time scales.
- Measurement and control of microstructures improved understanding to control parameters for e.g. biological APIs, nanomaterials, phase separations in weak gel systems and understand the effects of temperature, humidity and oxygen on chemical stability and packaging choice

**2. Closing the loop:** Data-rich formulated product and process design.

- Prediction on scale down for fundamental understanding, measurement and design. For processes such as granulation, film-forming, and highshear mixing.
- Build a tablet. Design a predictive model for solid multicomponent formulations, such as pharma tablets, dishwash and laundry tablets, catalyst pellets, agrochemical granules and dry foods).
- Data management: Improved data capture, management and Integration, validation, analysis and modelling, visualisation, optimisation, standardisation. This would lead to a standardised process and infrastructure to use when designing new products or processes.
- **3. Sustainability:** Design formulations for a more sustainable future.
- Bio-derived ingredients for film forming development of formulation principles for film forming for new bioderived ingredients, to provide sustainable routes for films for coatings, lubricants, cosmetics etc.
- Integrating formulation with synthesis finding ways redesign process and integrate synthesis of active ingredient with formulation (e.g. tablet, granule, suspension).
- Raw materials resource for formulators design database for formulators to enable increased use of more sustainable ingredients.
- **4. Process:** Process design and manufacture of formulated products.
- Manufacturing and operability for quality and cost developing inline measurement techniques to allow real-time monitoring (and flexible processing) of complex, highly viscous liquid products.
- Innovative Manufacturing Processes for Agility in Scale: Scale down of continuous processes, energy efficient continuous processing. Model process in advance "in silico".
- Designing a capability hub in formulation manufacturing which links industry needs with existing facilities and expertise in industry and academia.



Most of these projects are now being developed further by various consortia for submission to the TSB Collaborative R&D competition in formulated products. For the other projects, because of their scale, complexity or long-term nature, alternative delivery routes are also being explored e.g. self-funded, EPSRC and Formulation Centre.

During the workshops it was evident that some companies were reasonably aware of what technically needed to be done to address the challenges discussed. However they were less clear on whom to collaborate with to achieve their objectives. This reinforces the need to provide capability and resource to signpost expertise, wherever it exists and to provide companies with a menu of technologies, personnel, expertise and equipment, in order to make progress on any one project.

# MAPPING THE SCIENCE AND TECHNOLOGY CAPABILITIES AND NEEDS IN FORMULATION

The work conducted in workshops and interviews to define a strategic project portfolio which is described in the previous section allows a map of the most pressing industrial needs in formulation science and technology to be constructed. In the following tables, these needs are categorised and broken down under the five themes for formulation which have been used for the earlier analysis (Radical Formulated Product Design; Formulation for Delivery; Radical Formulation Process Design; Formulation for Stability and Formulation for Sustainability). Against the needs are described some examples of the beneficial outcomes (problems solved, opportunities realised) which industry can realise as these needs are met. Against each need is included an indication of which scientific and technological capabilities will required in order to meet those needs.

The capabilities considered were:

- Colloids, particles and soft matter
- Solids formulation and processing
- Process technology and scale-up
- High throughput experimentation
- Informatics, data and modelling
- Characterisation and measurement



| What is the scientific or technological need?  | Why is it important?(examples of outcomes)   |  |  | What capab                            | ilitites are requ                     | uired?                                |  |
|--|--|--|--|---------------------------------------|---------------------------------------|---------------------------------------|--|
|  |  | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics,<br>data and<br>modelling | Characterisation<br>and<br>measurement |
| 1. Radical Formulated Product Design:  |  |  |  |                                       |                                       |                                       |  |
| Improved uptake and use of multiscale modelling methodology<br>to predict useful properties in formulated products with complex<br>microstructure. | To enable faster and more robust development of new formulations. To generate variety in a product portfolio to enable effective exploitation in new and developing economies or sectors, or to respond to different conditions, equipment and end-uses.   | •                                      | •  |                                       | •                                     | •                                     | •                                      |
| Improved algorithms for mesoscale modelling and simulation of complex products e.g. particulate systems.   | To target formulation development to meet specific customer<br>needs, quickly and with competitive advantage. To increase<br>flexibility in manufacturing for fast product changes and small<br>volumes. To increase consistency and quality in a multi-product,<br>multi-component portfolio. To enable of scale-up/ scale-down<br>predictions. To achieve new IP and a competitive edge for a<br>product family. | •                                      | •  |                                       | •                                     | •                                     |  |
| Better use of modelling and simulation techniques to design completely novel micro- and nanostructures.  | To build complex microstructures to give the predicted desired properties (e.g. mouth feel, texture, safety, rheology, tribology)  | •                                      |  |                                       | •                                     | •                                     | •                                      |
| Development of new characterisation methods for quicker and<br>more meaningful evaluation of formulations in development or<br>production.         | To enable faster development of new formulations with better tuned performance in end-use application.   | •                                      | •  |                                       | •                                     | •                                     | •                                      |
| Development of lab methods that better reflect end-use application or sensorial properties.  |  |  |  |                                       | •                                     | •                                     | •                                      |
| Improved uptake by companies of High Throughput Experimentation in Formulated Product Design.  | To trial, test and model to aid the development of new applications<br>of fundamental sciences. To better understand and exploit in<br>practice the product and process behaviours.  | •                                      | •  |                                       | •                                     | •                                     |  |
| Improved methodologies and algorithims for DoE an HTE data handling.   | Formulation robustness - to make better use of HTE and define wider areas of experimental space within which formulations can be optimised.  | •                                      | •  |                                       | •                                     | •                                     |  |
| Improved (miniaturised) measurement techniques for HT.   | To make use of small scale measurements that can be representative of bulk physical properties or real life end-user criteria.   | •                                      | •  |                                       | •                                     | •                                     | •                                      |
| Improved handling and preparative technology in HTE  | To widen the range of products which can be developed and optimised using HTE.   | •                                      | •  |                                       | •                                     |                                       |  |



| What is the scientific or technological need?   | Why is it important?(examples of outcomes)  | What capabilitites are require         |  | uired?                                |                                       |                                       |
|---|---|--|--|---------------------------------------|---------------------------------------|---------------------------------------|
|   |   | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics,<br>data and<br>modelling |
| 1. Radical Formulated Product Design Continued  |   |  |  |                                       |                                       |                                       |
| Improved capture, analysis management and use of data from<br>laboratory and process. To include data capture, management<br>and litegration, validation, analysis and modelling, visualisation,<br>optimisation and standardisation. | To create (e.g. for personal care and pharma formulation) a standardised process and infrastructure, a source of reliable information to access when designing new products or processes "data you can trust" and compatibility with standard informatics software.   |  |  |                                       | •                                     | •                                     |
| Improved prediction at scale (scale down) for fundamental understanding, measurement and design.  | To devise a tool ("build a tablet") to design solid multicomponent<br>formulations (e.g. pharma tablets, dishwash and laundry<br>tablets, dry foods). The ideal tool would start "in silico" and<br>use measurement and modelling to predict scalability of<br>manufacturing and handling, dissolution, disintegration,<br>stickiness/cohesion, mechanical and chemical properties. | •                                      | •  | •                                     | •                                     | •                                     |
| Improved uptake of state of the art and established characterisation methods in routine formulation development.  | To benefit from in-process optimisation of formulation - i.e. optimisation of design during production.   | •                                      | •  |                                       |                                       | •                                     |

| What is the scientific or technological need?  | Why is it important?(examples of outcomes)   | What capabilitites are required?       |  |                                       |                                       |                                       |  |
|--|--|--|--|---------------------------------------|---------------------------------------|---------------------------------------|--|
|  |  | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics,<br>data and<br>modelling | Characterisation<br>and<br>measurement |
| 2. Formulation for Delivery:   |  |  |  |                                       |                                       |                                       |  |
| Improved understanding and design of ingredient interactions<br>in formulation (i.e. interactions with other ingredients, surfaces,<br>barriers and targets) and better integration of ingredient design<br>with formulation design. | To create improved effects in products, e.g. lubricants with<br>increased engine lifetime and efficiency, detergents with<br>functionality at ambient temperatures and lower water use, foods<br>with reduced sugar, salt or fat, reduced salt, sugar, fat, medicines<br>with enhanced bioavailability.  | •                                      | •  |                                       |                                       |                                       | •                                      |
| Improved design of release and delivery mechanisms.<br>Improved design, control and manufacture of desired complex<br>nano- and microstructures.   | To create and develop new product forms such as targeted<br>pharma and healthcare products for specific patient types<br>(formulation for personalised medicine). To produce improved<br>delivery products such as controlled and targeted release<br>formulations; encapsulation, protection and release of effect<br>ingredients. To enable product line extension and differentiation<br>via new dosage forms, improved performance. To enable<br>nanotechnologies for improved functionality (nanosurfaces,<br>nanoparticles). | •                                      | •  |                                       |                                       |                                       |  |
| Manufacturing of complex delivery systems.   | To enable better delivery of an active via a more (cost) effective product. To provide multi-API combination medicines with a variety of controlled release profiles.  | •                                      | •  | •                                     |                                       |                                       | •                                      |





| What is the scientific or technological need?  | Why is it important?(examples of outcomes)   |  |  | What capab                            | pilitites are requ                    | uired?                               |
|--|--|--|--|---------------------------------------|---------------------------------------|--------------------------------------|
|  |  | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics<br>data and<br>modelling |
| 3. Radical Formulation Process Design:   |  |  |  |                                       |                                       |                                      |
| Improved use of real-time in-process measurement to optimise manufacture.  | To better integrate formulation development with formulation<br>manufacturing - for more rapid product and process development<br>and better process and product robustness.   |  |  | •                                     |                                       | •                                    |
| Improved demonstrator and scale-up facilities for novel formulation manufacturing technologies.  | To make better use of e.g. particle design/synthesis. crystalisation/<br>precipitation, microencapsulation, nanostructure synthesis,<br>microfluidics, flow-cell, continuous processing).  | •                                      | •  | •                                     |                                       |                                      |
| Better ability to model a process before manufacturing or building anything.   | To enable manufacturing technologies that minimise costs, energy, water, an raw material usage.  | •                                      | •  | •                                     |                                       | •                                    |
| Better ability to scale processes (e.g. granulation, dispersion, coating extrusion, spray drying) up or down (agility in scale), more reliable (in Silico) process design modelling. Prediction of behaviours during scale-up and/ or scale down component interactions, rheology, morphology.                             | To improve predictability when scaling up or down. Increased<br>use of continuous processes, enable energy efficient<br>processing. Enable innovative manufacturing process for agility<br>in scale. Produce scalable process technology for formulation<br>manufacturing - build on distributed supply chains (e.g. a finished<br>formulation assembled near point of use). | •                                      | •  | •                                     |                                       | •                                    |
| Improved models for improved (waste, cost, quality)<br>manufacturing. Betterunderstand the formulation space<br>of operability of a process. Understand better how 'dirty'<br>materials behave in real systems. Better understanding of<br>fundamentals and the development and validation of inferential<br>measurements. | To optimise manufacturing operability for quality and cost. To<br>understand and control batch to batch variations and limitations<br>better. To improve quality by design methods for better prediction<br>of "formulatability" and manufacturability.  | •                                      | •  | •                                     |                                       | •                                    |
| Improved novel inline measurement techniques to enable real-<br>time monitoring (and flexible processing) of complex, highly<br>viscous liquid products.   | To improve cost an quality of formulation manufacturing.   |  |  | •                                     |                                       | •                                    |
| Provision of demonstrator facilities for new process technologies and measurement systems.   | To enable companies to elevate novel processes with lower<br>commercial risk and cost. To produce prototype amounts for pre-<br>marketing purposes using novel technologies.   |  |  | •                                     |                                       |                                      |
| Provision of a process technology capability hub in information.   | To allow companies use of a resource which analyses their needs,<br>matches them with existing provision or enables any gaps to be<br>filled.  |  |  | •                                     |                                       | •                                    |





| What is the scientific or technological need?  | Why is it important?(examples of outcomes)  |  |  | What capab                            | oilitites are requ                    | uired?                                |
|--|---|--|--|---------------------------------------|---------------------------------------|---------------------------------------|
|  |   | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics,<br>data and<br>modelling |
| 4. Formulation for Stability:  |   |  |  |                                       |                                       |                                       |
| Better understanding and control of physical mechanisms and<br>multi-phase behaviours which influence product stability (solid,<br>liquid products). Practical application of thermodynamics and<br>kinetics to phase separations in individual systems  | More stable products based on biological APIs, nanomaterials<br>and weak gel systems. Enabling stability prediction of surfactent<br>microstructures and precise rheology control. Better prediction<br>of effects of changing components or conditions during<br>development and to react to changes in manufacture and use. | •                                      | •  |                                       | •                                     | •                                     |
| Improved understandings and control of multi-component interactions which influence product stability (solid, liquid).   | Better products and shorter experimental cycles through<br>understanding and control of the effects of temperature, humidity<br>and oxygen on chemical stability and packaging.   | •                                      | •  |                                       | •                                     | •                                     |
| Development of a priori theoretical and modelling methods<br>to enable physical stability prediction in silico (solids, liquids,<br>particulatesystems). Adding functionality to modelling and<br>simulation multi-scale modelling algorithms to access much<br>longer timescales to enable precise control of stability from<br>seconds to years. | Develop more stable products via measurement and control of microstructures.  | •                                      | •  |                                       | •                                     | •                                     |
| Improved microstructure measurement and control across<br>length scales for desired mechanical and stability properties of<br>finished products.   |   | •                                      | •  |                                       | •                                     | •                                     |
| Improved and integrated data handling, simulation,<br>experimentation, prediction and modelling systems to enable<br>stability control over scales and timescales.   |   | •                                      | •  |                                       | •                                     | •                                     |

| What is the scientific or technological need?  | Why is it important?(examples of outcomes)   | What capabilitites are required?       |  |                                       |                                       |                                       |  |
|--|--|--|--|---------------------------------------|---------------------------------------|---------------------------------------|--|
|  |  | Colloids,<br>Particles,<br>Soft Matter | Solids<br>formulation<br>and<br>processing | Process<br>Technology<br>and scale-up | High<br>throughput<br>experimentation | Informatics,<br>data and<br>modelling | Characterisation<br>and<br>measurement |
| 5. Formulation for Sustainability:   |  |  |  |                                       |                                       |                                       |  |
| Improved characterisation and prediction of the properties and interactions of complex and impure ingredient mixtures.                                     | Enhancing stability of bio actives formulation and use. Allows customising and targeting for 100% product effectiveness in use.  | •                                      | •  | •                                     | •                                     | •                                     | •                                      |
| Development of a supply chain for renewable ingredients for formulation.   | Allows complete redesign of a product and the processes in<br>its whole supply chain for the minimum environmental impact.<br>Enables better use of natural and sustainably sourced raw<br>materials for effect. Enabling use of more acceptable solvents<br>in formulations. Enables building of raw material resource<br>(database) for formulators to allow increased use of more<br>sustainable ingredients. |  |  | •                                     |                                       | •                                     |  |
| Development of formulation principles for film forming that apply for new bio-derived ingredients.   | Enable development of bio-derived ingredients for film forming to provide real sustainable routes for easier application and removal of films (coatings, lubricants, cosmetics, etc).  | •                                      | •  |                                       | •                                     | •                                     | •                                      |
| Improved characterisation and predictive methods to deal with variability in raw materials in formulation design and manufacture.                          | Enables improved formulation robustiness and cost-effective slot-<br>in of new renewable ingredients.  | •                                      | •  |                                       | •                                     | •                                     | •                                      |
| Development of process design tools and models for<br>integration of chemical synthesis (primary manufacture) with<br>formulation (secondary manufacture). | Enables integration of formulation with synthesis. Step, e.g. for pharma API synthesis and formulation of tablet, granule or suspension in one step-remove cost, reduce environmental impact, time.  | •                                      | •  | •                                     | •                                     | •                                     | •                                      |
| Development of novel separation processes.   | For complex mixtures this enables the components of a formulation to be recovered and re-used.   | •                                      | •  | •                                     |                                       |                                       | •                                      |





The tabulation of needs and capabilities provides an overview of which capabilities are required to make progress against challenges in the different areas of formulation. Capabilities in process technology / scale-up and high-throughput experimentation are needed for specific challenges, whereas the other capabilities are required in virtually all areas.

In order to plan any new investment in developing capabilities in formulation science and technology, it is first important to establish where existing capabilities already exist. Box 9 summarises the capabilities of the UK's major academic centres and institutes that are active in the science and technology to support formulation. Capabilities are indicated in five of the scientific themes outlined above which are of high relevance to the industrial formulation community. The sixth theme of measurement and characterisation is not included because in general it is well represented in all institutions and so does not act as a differentiator.

### Box 9 - UK Academic Centres active in Formulation

| Capabilities Table                        | Colloids,<br>Particles,<br>Soft Matter | Solids formulation | Process<br>Technology/<br>scale-up | HT | Informatics/<br>Modelling |
|---|--|--------------------|------------------------------------|----|---------------------------|
| University of Birmingham                  |  |                    |                                    |    | •                         |
| University of Bath                        |  |                    |                                    |    |                           |
| University of Bradford                    |  |                    |                                    |    | •                         |
| University of Bristol                     |  |                    |                                    |    | •                         |
| University of Cambridge                   |  |                    |                                    |    | •                         |
| The Centre for Process Innovation         | •                                      | •                  |                                    |    |                           |
| De Montfort University                    | •                                      |                    |                                    |    |                           |
| University of Durham                      |  |                    |                                    |    | •                         |
| University of Edinburgh                   |  |                    |                                    |    | •                         |
| University of Greenwich                   |  | •                  |                                    |    | •                         |
| University of Hull                        |  |                    |                                    |    | •                         |
| Imperial College London                   |  |                    |                                    |    |                           |
| Lancaster University                      | •                                      | •                  |                                    |    | •                         |
| Kings College London                      | •                                      | •                  |                                    |    |                           |
| University of Leeds                       |  |                    |                                    |    | •                         |
| University of Liverpool                   | •                                      |                    |                                    |    | •                         |
| Loughborough University                   |  |                    | •                                  |    |                           |
| University of Manchester                  |  |                    |                                    |    |                           |
| National Measurement Office/Institute     | •                                      | •                  |                                    |    |                           |
| University of Nottingham                  |  |                    | •                                  |    |                           |
| University of Sheffield                   | •                                      |                    |                                    |    |                           |
| Science and Technology Facilities Council |  |                    |                                    | •  |                           |
| Strathclyde University (incl.CMAC)        | •                                      | •                  |                                    |    | •                         |
| University of Surrey                      | •                                      | •                  |                                    |    | •                         |
| UCL (London School of Pharmacy)           |  |                    |                                    |    |                           |

This summary indicates that no single institution can provide all of the capabilities which might be required by industry. The important area of underpinning science covered by the first theme (colloids, particles and soft matter) is particularly well represented at a very wide range of institutions. The science and technology of solid formulation and processing is also well represented and in many cases these institutions also cover the first theme. There is more sparse coverage of the remaining three themes: Process technology / scale-up, high-throughput experimentation and informatics / data / modelling. In these themes only a small number of institutions can provide depth.

At this stage, the capabilities of the private sector (e.g. formulating companies, supply chain companies and contract research organisations) should also be mentioned. A summary of the UK formulation industry is given in the introduction and in general for reasons of confidentiality it is not usually possible to provide any more detail on the R&D capabilities of these organisations. However in the public domain are a number of initiatives and capabilities, including:

- Syngenta's high-throughput formulation robot, announced in 2010.
- Unilever's in-house high-throughput formulation capabilities as well as a major collaboration in this area with the University of Liverpool, announced in 2012.
- AkzoNobel's UK centres of expertise in colloids science and complex fluids.
- Major centres for pharmaceutical formulation development in the UK including solid processing and characterisation at AstraZeneca, GSK, Pfizer and Bristol Myers Squibb.

In addition to the major formulating companies, considerable R&D capabilities in the UK can be found in supply chain companies (e.g. Croda, Malvern Instruments) and at contract research laboratories (e.g. SCM Pharma, Molecular Profiles, Battelle).



| Кеу                      |   |
|--------------------------|---|
| Full / extensive / clear |   |
| Partial / more limited   | • |
| None or no information   |   |



# A FORMULATION CENTRE FOR INDUSTRY - HOW SHOULD IT WORK?

An important element of consultation with companies during the SIG was to explore the rationale and build the case for a Formulation Centre. This industry consultation helped to establish some very clear guiding principles for the Centre:

### Vision

the Formulation Centre should:

1. Be an open-access innovation centre for advanced formulated product design and manufacture comprising a central hub connecting to spokes of world class cross-sector expertise, technology and skills.

2. Enable companies to accelerate to market high value products and processes - underpinned by a step-change in predictive design capability built on a deep mechanistic understanding of complex formulated systems.

### **Open-access because**

- Shared physical space enables better creation of ideas and collaborations.
- Users should own their problems and bring part of the solution.
- The centre will deliver more value if it stimulates the whole UK formulation supply chain, from large companies to hi-tech SMEs.

### Innovation space because

- The gap which companies need help to fill is the applied development and implementation of new approaches to formulation
- Routine, low risk, development already happens within companies
- Blue-sky and curiosity-driven research happens in universities and companies.
- As value is realised, innovations should move out of the centre and become embedded in companies.

### Advanced formulated product design and manufacture because

Better integration of the product and process design stages is needed to deliver.

### A central hub connecting to spokes because

- The existing UK asset base in formulation needs to be built upon and fully exploited.
- There is a need for strong coordination and a strategic approach.
- Shared physical space enables better creation of ideas and collaborations.

### World-class expertise, technology and skills because

- The centre should be ambitious in size and scope.
- The highest standards are needed to compete globally.
- World class leaders attract others.

### Cross-sector expertise, technology and skills because

- Companies want to exchange and exploit insights and technologies embedded in other sectors.
- Next generation tools and technologies can be de-risked by working with non-competing sectors.

### Enabling companies to accelerate to market high value products and processes because

- Growth through technological innovation is the no. 1 priority.
- Regardless of the specific drivers and innovations, all formulating companies derive value from getting products to market faster.

#### Underpinned by a step-change in predictive design capability because

- Companies want to move away from the 'trial and error' approach to formulation.
- Incremental developments are undertaken already.
- This high-risk, high reward ambition requires a unique environment.

### Built on mechanistic understanding of complex formulated systems because

 Scientific understanding and overcoming complexity will enable the creation of new products and enable UK companies to differentiate themselves from global competitors.



# CREATING AN OPEN-ACCESS FORMULATION CENTRE FOR THE UK

Consultation with industry during the SIG enabled not only a vision and guiding principles for a Formulation Centre to be established, but also for a business plan to be developed. This section represents the executive summary of that business plan.

### **Business Plan Executive Summary**

The Formulation SIG has followed a systematic process of consultation, review and convergence that has gone through three cycles under the guidance of an industry leadership group made up of senior managers from a range of industrial companies. This document summarises the output of the consultation process and represents a business plan to create and sustain an Open-access Formulation Innovation Centre for the UK.

### The vision is to create:

An Open-access Innovation Centre

for

Advanced formulated product design and manufacture comprising

A central hub connecting to spokes

of

World class cross-sector expertise, technology, equipment and skills

# that

Enables companies to accelerate to market high value products and processes

# underpinned by

A step-change in predictive design capability built on

A deep mechanistic understanding of complex formulated systems



### The strategic objectives for the centre are:

- To stimulate significant value for the UK by accelerating the development, manufacture and application of next generation formulated products by 2020
- To build a critical mass of world-class capability and deliver unique collaborative innovation projects aligned to the strategic needs of, and otherwise inaccessible to, UK industry partners from multiple formulating sectors
- To create a secure open-innovation environment enabling cross-sector knowledge and technology transfer, and identification and co-development of shared future needs and solutions.
- To identify, integrate and facilitate access to existing company, innovation centre and academic value-adding assets to allow partners to access the best people and technologies wherever they are.
- To establish a closed-loop innovation supply chain from market to research and back
- To unite industry, government and research in a shared goal and plan to make the UK an attractive place to invest in formulation.

Formulation innovation themes have been identified, validated by the SIG industry leadership group, and will form the framework for the strategic direction and technical priorities of the centre.

- Radical Formulated Product Design
- Formulation for Delivery
- Radical Formulated Process Design
- Formulation for Stability
- Formulation for Sustainability

The formulated products market in the UK is about £180 billion pa with an additional potential market for UK companies of up to £1000 billion globally. Formulated products are used in markets as diverse as: Aerospace, Automotive, Pharmaceuticals, Home and Personal Care Products, Agrochemicals, Foods, Coatings, Construction Chemicals and Industrial Process Chemicals. Multinationals such as P&G, Unilever, Henkel, Reckitt Benckiser, J&J, L'Oreal, Bayer, GSK, Pfizer, Novartis, BMS, AstraZeneca, Syngenta, AkzoNobel, PPG, Nestle and Kraft depend on the sales of formulated products to create value within their businesses.

These combined sectors contribute a significant surplus to the UK balance of trade and represent about 30% of total UK manufacturing; employing about 1.5 million people. Many of the roles in the industry are high value jobs with at least 25% requiring graduate level skills. At least £2bn of Formulationrelated R&D is expended annual by UK companies to achieve sustained growth and this is estimated to contribute to an increase in GVA by a factor of between 3 and 10. Similarly, safeguarding the 1.5m relevant workforce with the potential of growth in technically skilled employees is a significant outcome, as is the support of leading R&D laboratories.

The market for the centre i.e. income through 'new' cross sector external R&D collaborations with UK companies is estimated in the medium term to be up to £10m p.a.

The proposed centre structure will have four core elements that will create an integrated nationally significant activity:

- A physical centre: This will be the hub of the national centre it will provide central management, a collaboration space and a location for the development and proving of next generation formulation technologies. It will house a core team of scientists, engineers and business experts with capability and experience in a wide range of keys areas of science and technology. In addition to core employees, it will house a dynamic and flexible group of secondees drawn from partner companies and strategic spokes.
- An alliance of delivery partners: These will be a combination of industry partners and strategic spokes. Together they will provide, and where appropriate house, leading assets, people and knowledge in key specialist platform areas. The delivery partners will be a combination of industry members, RTOs and universities. They will have deep knowledge and skills in specialist areas and be committed long-term to collaboration in formulation.
- A set of core development projects and programmes. Developed by the partners within the National Formulation Centre to build capabilities of national significance which can be conducted in a pre-competitive or a multiindustry non-competitive environment. Projects will be co-ordinated by the hub team but would bWe carried out across both the hub and spokes.
- Integrated Communities of Practice: The centre will have a number of communities that facilitate the sharing of best-practice between industry sectors to enhance the performance of the UK formulation industry. The communities will provide access to, and leadership of, an extended UK formulation network. They will also provide a platform for the definition and creation of future programmes.



Delivery of the centre will be via the UK's High Value Manufacturing (HVM) Catapult centre and in turn hosted by the Centre for Process Innovation (CPI).

The hub will be located at CPI, Wilton Centre or Daresbury Science and Innovation campus.

Priority targets for industry partners will come from the following sectors:

Home and personal care, food, pharmaceuticals, coatings, agrichemicals and oil additives and lubricants.

The priority strategic spokes targeted are: University of Leeds, Daresbury – Science and Technology Facilities Council, University of Birmingham, University of Nottingham and CPI.

| Membership type                           | Target number of members at the end of year 2 | Contribution as a combination of<br>cash and in-kind   |
|---|---|--|
| Tier I industry partner                   | 5   | £250k per year committed for 2 years   |
| Tier II industry partner                  | 15 (including at least 5 SMEs)                | Between £10k/yr and £50k/yr based<br>on a sliding scale related to turnover<br>committed for 2 years |
| Tier III industry partner                 | >50   | £1k/yr   |
| Strategic spokes & demonstration partners | 5 Universities or RTOs, 4 SMEs                | In-kind contribution   |

Contributions to the centre will be across a wide and flexible range of options. These could be: direct cash, physical equipment, giving centre members and partners direct access to existing equipment and the secondment of people to the centre by member companies. Demonstration partners will be encouraged to make equipment available to the centre.

Governance and identity: The Formulation Centre will be semi-autonomous with its own brand, management team, steering group and technical programme group. The Steering Group will be made up of Tier 1 members plus the HVM Catapult CEO, a CPI executive and representatives for other membership tiers. It will guide the Formulation Centre by defining strategic direction and core technical programmes and investment.

| Priority | Theme area     | Product description  |
|----------|----------------|--|
| 1        | Stability      | Data handling  |
| 2        | Process Design | Move to Continuou  |
| 3        | Delivery       | Projects to develop  |
| 4        | Stability      | Control of structure   |
|          | Stability      | Understanding of I   |
|          | Product Design | Use HT technologi<br>applications of fund<br>process behaviour |
|          | Product Design | Enable better deliv  |
| 5        | Process Design | Prediction at Scale<br>measurement and                         |
| 5        | Process Design |  |

A schematic diagram of the proposed structure for the National Formulation Centre is shown below.

the

Other potential spokes (subject to further development of the centre proposal) are: University College London, Imperial College London and University of Bristol

The SIG consultation has defined a 3 tier membership model for the centre. The different Tiers will have different levels of access and involvement depending on the member contributions. In addition to their involvement in the core shared programmes all members will have improved access to opportunities to become members in collaborative R&D projects within TSB, EC and other funding bodies as well as the opportunity to carry-out fully funded company specific programmes of work. The following targets for membership numbers and fees have been defined in the first 2 years. Securing the launch partners will form a major part of the next phase of centre development.

The SIG consultation programme has included a number of collaborative workshops and many individual one to one meetings with companies, experts and potential partner spokes. A number of priority projects that will direct the early activity within the centre have been identified and are listed in the table below:

# on

us Processing from Batch

p new product forms

es

Individual components

ies to trial, test and model to aid development of new indamental sciences and/or understand product and rs in practice

very of an active via a more (cost) effective product

 / Scale Down for fundamental understanding, design The centre staff is forecast to grow to a target critical mass of over 25 people in 3 years and will be made up from a combination of direct employees and people seconded from member companies and strategic spokes.

An initial financial plan has been prepared and is detailed in the full business plan. This forecast is the base case and will be developed further as project outlines are developed further with the partners.

The plan assumes that company contributions will be matched by capital and revenue from the public sector through the TSB Catapult programme to establish and support the National Formulation Centre.

The aspiration and planned expenditure profile of the centre is to move to a 1/3:1/3/1/3 split between private:public/ private:public funding that is consistent with Catapult centres.

A risk analysis and set of KPIs have also been proposed and are outlined in the body of the business plan.

The delivery plan for the centre is outlined in the full plan. This plan starts with the short-term activities detailed below. The target launch date is April 2014.



| Activity  | Target completion date |
|---|------------------------|
| Secure establishment funding of and 'in principle' commitment from the TSB/BIS/HVM Catapult | Q3 2013                |
| Draft memorandum of understanding for partners/stakeholders                                 | Q3 2013                |
| Secure 'in principle' commitment from founder tier I members                                | Q3 2013                |
| Secure 'in principle' commitment from initial spokes for the centre                         | Q3 2013                |
| Set the location of the Formulation Centre Hub  | Q4 2013                |
| Define the initial project programme  | Q4 2013                |
| Launch the National Formulation Centre  | April 2014             |

It is proposed that the current SIG team is retained to facilitate these activities with leadership gradually transitioning from Chemistry Innovation KTN to CPI/HVM Catapult.

It is proposed that the delivery phase is resourced through a combination of industrial secondments and the TSB/HVM Catapult funds.

# COLLABORATIVE R&D COMPETITION IN FORMULATION

In the introductory section to this report some of the barriers to effective innovation in formulation have been described. These include an over-reliance on trial and error and empirical methods; difficulty in applying and embedding scientific understanding to formulation challenges and a lack of effective collaboration mechanisms (e.g. multi-party cross-industry, SME involvement and company-academic). For these reasons, the SIG management team, guided by the SIG's Industry Leadership Group, and using the outcomes of the Project Building Workshops, input into a call document on behalf of the Technology Strategy Board for a collaborative R&D competition in formulation.

The TSB call model ensures that successful project proposals are focused on clear commercial outcomes, rather than on purely scientific endeavours. Such TSB funding is intended to bridge the gap between the basic research typically carried out in academic institutions and the nearto-market development carried out in companies. As such this funding is intended to de-risk a project and stimulate the implementation of new and innovative approaches. The call document specifically encourages applications which address the barriers to innovation in formulation described above. Lead applicants must be industrial partners. Two sorts of proposal are possible, feasibility studies (typically project size up to £100,000) and collaborative R&D projects (up to £1 million project size).

The scope for the call was deliberately kept broad. This was to encourage proposals from the very wide range of industries which use formulation science and technology, as well as to encourage cross-industry collaborations. However it was considered essential that project proposals must have at their heart the design, manufacture or end-use of a complex formulated product.

The technological themes to which project proposals should be aligned were based on the five themes developed with the SIG's Industry Leadership Group and which underpin the project portfolio for the Formulation Centre and which is described elsewhere in this report. The five themes (Radical Formulated Product Design; Formulation for Delivery; Radical Formulation Process Design; Formulation for Stability and Formulation for Sustainability) are summarised in Box 9.



The proposal to run a collaborative R&D competition in formulation was approved by the Technology Strategy Board and the competition was launched in March 2013, with a deadline for first stage proposals in June 2013. Successful projects are expected to start around the end of 2013. In addition to up to £5 million of funding available from the Technology Strategy Board, a sum of up to £1 million has been made available by EPSRC which is intended to

## Box 9 The Five Technological Themes for Formulation

**Radical Formulated Product Design:** Methods to accelerate the design and optimisation of new formulated products throughout the chain from R&D to production and the market. Exploiting convergence and advances in measurement, modelling and simulation, experimental design, data management/ informatics, automation and miniaturisation. Outputs will enable better fundamental understanding, extended coverage of experimental space, accelerating R&D and smoothing the path of new product development and launch.

**Formulation for Delivery:** Technologies which enable or improve the precisely controlled and targeted use of ingredients or which provide radically new formulation architecture or product microstructure. Approaches could include the development and innovative uses of encapsulation, polymer, surfactant or nano-material technologies.

Radical Formulation Process Design: Technologies which can be implemented in a production environment to provide better products, improved quality or a significant economic or environmental benefit. Radical approaches may be paradigm-led e.g. continuous, flexible, adaptive, distributed, concurrent product and process design, integrated primary and secondary manufacturing. Examples of novel process technologies could include high-intensity mixing, membrane technologies and microfluidic arrays. Innovative developments and use of in-process analysis, measurement, modelling and process controls are also in scope.

**Formulation for Stability:** New methods for prediction, measurement, characterisation, control and optimisation of the stability of complex products which can bring economic or environmental benefits. Methods may be implemented in R&D and/or manufacturing/QC environments. Business benefits may include faster new product development, more robust manufacture, regulatory compliance, supply chain management and improved shelf-life claims.

**Formulation for Sustainability:** Integrated product and process design which considers ingredient sources, the impact of production processes as well as the end-use of formulated products. Projects should deliver environment, societal and business benefits. Integrated approaches which consider all aspects: Ingredients and their sources, production, transport, storage, end-use, disposal, recycling and re-use.

support projects where the need for fundamental research is demonstrated.

The official competition briefing document - 'Formulated Products – Meeting the Product and Process design challenge' – is available from the competitions section of the TSB website www.innovateuk.org

# SKILLS DEVELOPMENT AND TRAINING TO SUPPORT INNOVATION IN FORMULATION

In the introduction to this report it is explained that companies have for some time experienced a patchy provision of skills and training in formulation. The reasons for this include the fragmentation of formulation by academic discipline and by industry. For instance in a survey conducted amongst companies by the Intelligent Formulation Network in 2011 and communicated subsequently it was found that skills gaps exist in formulation science amongst technical and R&D personnel. Companies reported that university courses in general don't cover much industry relevant formulation science and technology. Within companies formulation knowledge is held by experienced individuals with industry specific knowledge. This means that handover of knowledge to successors is not always easy - internal company experts have little time to do this and there is very little formalised training internally in companies. A number of well-established training courses and qualifications exist (Box 10) and where external training in formulation is available it is seen as potentially effective but it is often ad hoc and not part of a coherent programme. Companies also find it challenging to find the right experts to deliver the right material in an effective and timely manner.

Against this backdrop it was clear that the Formulation SIG should consider the potential negative impact that a lack of suitable skills amongst the UK's formulation R&D practitioners could have on the ability of companies to innovate in formulation. As skills and training are not formally part of the remit of the Technology Strategy Board, the SIG work package on this subject acted to ensure communication and co-ordination of several existing activities in the area of formulation skills and training with the innovation activities of the SIG. Engaged on this work package were Cogent Sector Skills Council and iFormulate Ltd, with support and guidance from companies as well as from professional bodies such as IChemE and the Royal Society of Chemistry. Towards the end of the work package further guidance and support was provided by the Academy of Pharmaceutical Sciences.

Two major activities were undertaken in this area. In the first of these, Cogent SSC engaged iFormulate Ltd to consult with employers in the formulating industries in order to produce three new "Gold Standards" for job roles in formulation. Gold Standards are in essence a competency framework for line managers, employees and human resources professionals and are available for a wide range of job roles in the process industries. The Gold Standards cover four areas of competency: technical, business improvement, compliance and functional/behavioural. In each of these areas the expected standards of competency are defined. Companies can then use these competency frameworks for a number of purposes, including employee CPD planning; succession planning; benchmarking against industry standards; identifying skills gaps; identifying required qualifications and training; developing role profiles and job descriptions; aiding recruitment and building competence assurance. During the consultation with employers three initial iob roles were identified and selected for the drafting of Gold Standards:

Formulation Scientist: Research & Development, New Product Development

Senior Formulation Technician: Research & Development, New Product Development

**Process Technician Formulation** 

#### **Box 10**

Examples of Existing Training and Qualifications (Graduate Level and above) relevant to Formulation

### **Graduate and Postgraduate Qualifications**

- Diploma in Cosmetic Science by Distance Learning, Society of Cosmetic Scientists
- · Pharmaceutical and Cosmetic Science BSc, De Montfort University
- M.Sc. in Formulation Science. University of Greenwich
- MChem Chemistry for Medicines Development, University of Bradford
- MSc Pharmaceutical and BioPharmaceutical Formulations. University of Sunderland
- MSc Pharmaceutical and Analytical Science, University of Huddersfield
- MSc Cosmetic Science, London School of Fashion
- Advanced Chemical Engineering Masters. University of Birmingham
- Eng. D. In Formulation Engineering, University of Birmingham

#### Training Courses

- Principles of Colloid Science, Formumetrics / Bristol
- eLearning in Formulation Technology, Formumetrics / Bristol
- Fundamentals of Formulation Science and Technology, Leeds
- Chemical Engineering for Scientists, **IChemF**
- Fundamentals of Process Safety, IChemE
- Particle Technology, **IChemE**
- · Formulating with Surfactants, BACS
- Rheology, BACS
- Granulation Course, University of Sheffield
- Non Aqueous Colloids, University of Leeds
- Particle and Powder Characterisation, University of Leeds
- Rheology of Suspensions/Dispersions, University of Leeds
- Formulation for poorly soluble APIs, Pharmaterials
- Professional Paint Formulation, PRA

The Gold Standards are now available from Cogent SSC for these roles for companies to use and mean that for the first time it is possible to build a structured framework of skills and technical competencies for individuals in formulation roles. Further additions to the set of job roles in the formulation area are expected in the near future.

The second major activity undertaken during the SIG period was designed to build upon the Gold Standard work and construct a fully integrated partnership for skills and training of lasting benefit to industry. In March 2013 announced a major proposal for an Industrial Partnership for the sciencebased industries. The proposed partnership - to be led by GSK and co-ordinated by Cogent SSC - was submitted for funding to UKCES, the government agency for skills funding in March 2013. The Industrial Partnership will cover several industries and underpinning technologies. Importantly for the formulation community however, is that formulation technology will be included amongst those underpinning technologies and most of the formulating industries are included as well.

The final form of the Industrial Partnership has yet to be determined and this will be strongly influenced by the companies that join the Partnership. However in the area of formulation it is expected that the Partnership will construct a full modular curriculum for a range of job roles (from

#### Box 11 - Draft Formulation Curriculum

| Job Roles in Formulation               | Programme                              | Level                    |
|--|--|--------------------------|
| Senior/General Management              | A1 – A3 Formulation Awareness          | General                  |
| Functional Management                  | I1-I9 Introduction to Formulation      | Vocational               |
| Formulation Scientist R&D              | L1-L15 Laboratory Formulation          | Vocational               |
| Senior Formulation Technician          | M1-M15 Formulation Manufacturing       | Vocational               |
| Process Technician Formulation         | Q1-Q3 Formulation Quickstart           | Graduate and above       |
| Process Operative and Supervisor       | S1-S21 Formulation Science and Technol | ology Graduate and above |
| QA, Technical Service, other Technical | F1-Fn Advanced Formulation             | Graduate and above       |
| General Staff - non Technical          |  |                          |

### Example Career Pathway: **Process Technician Formulation**

(A1 – A3 Formulation Awareness) 11-19 Introduction to Formulation M1-M15 Formulation Manufacturing

Career Progression Options: Full programme or modules from:

L1-L15 Laboratory Formulation Q1-Q3 Formulation Quickstart S1-S21 Formulation Science and Technology Programmes could form part of vocational qualifications such as Intermediate. Advanced and Higher Level Apprenticeships leading on to HNC/HND or foundation degree

Could form part of academic qualifications e.g. BSc, M.Chem, MSc.

| Programme                                 | Level              |
|---|--------------------|
| A1 – A3 Formulation Awareness             | General            |
| 11-19 Introduction to Formulation         | Vocational         |
| L1-L15 Laboratory Formulation             | Vocational         |
| M1-M15 Formulation Manufacturing          | Vocational         |
| Q1-Q3 Formulation Quickstart              | Graduate and above |
| S1-S21 Formulation Science and Technology | Graduate and above |
| F1-Fn Advanced Formulation                | Graduate and above |
|   |                    |



vocational to senior professional) in formulation and then link existing and new training provisions from a range of providers to those modules. Where there are gaps in provision then modules and programmes will be commissioned from providers to fill those gaps. Where appropriate and where the industry partners determine that it is desirable, schemes for accreditation (such as chartered or registered status) will be devised for certain qualifications. In this respect it is expected that professional bodies such as IChemE; the Royal Society of Chemistry; the Academy of Pharmaceutical Sciences as well as other such bodies will become involved in devising suitable qualification standards.

In order to stimulate industry engagement in the proposed Industrial Partnership for skills and training, and to gain company feedback Cogent SSC commissioned iFormulate Ltd to draft an outline curriculum for formulation science and technology and this was launched in March 2013. The draft curriculum covers eight typical vocational and professional job roles (including the three roles for which Gold Standards have so far been devised) and outlines the curriculum for seven modular programmes. These job roles and modular programmes are shown in Box 11 which also provides an example of how modules and programmes could be linked together to form a typical career pathway.

It is expected that the draft formulation curriculum will be developed and refined as the Industrial Partnership is implemented.

Finally the Formulation SIG recognised further opportunities for skills and training in formulation which could arise from the establishment of a Formulation Centre for industrial innovation. In particular the proposed Formulation Centre could act as a base for some formulation training activities and the Centre could or should be linked to a new EPSRC Centre for Doctoral Training.

# REPRESENTATION, ACTIVITIES AND MANAGEMENT OF THE FORMULATION SPECIAL INTEREST GROUP

Industry Leadership Group and Company Engagement

The Industry Leadership Group (Box 12) was constituted in order to provide strong guidance for the SIG management team and to maximise contact and quality of inputs from a large and varied UK formulation community. The role of the Industry Leadership Group, which met several times during the course of the SIG, was to steer and validate the SIG activity and outputs and to working towards a ready-made consortium for post-SIG collaboration.

## Box 12

Industry Leadership Group (ILG)

Afton Chemical Ian Bell, R&D Director (Engine Oils)

## AkzoNobel

Graeme Armstrong, Executive Committee, Research, Development and Innovation (chair) Stephen Davies, Director, RD&I John Carroll, Director, RD&I

AstraZeneca Mike Hannay, VP Medicines Development Paul Stott, Director of Formulation Science

**Bristol Myers-Squibb** John Jones, Research Scientist Peter Timmins, Executive Director

## GlaxoSmithKline

Peter Blenkiron, Director, Skin Health R&D (Consumer Health) Jo Craig, VP, Formulation, Process & Analysis, UK (pharmaceuticals) Karen Lewis, Technical Director

# HARMAN Technology

Trevor Rhodes, Head of R&D **Pfizer** Alastair Coupe, Senior Director, Pharmaceutical Sciences

Procter and Gamble Euan Magennis, Innovation and Technology

**Revolymer** Terence Cosgrove – Founder

Syngenta Mike Bean, Formulation Technology Group Leader

Julie McDonald, Formulation Team leader

Ian Howell, High Throughput Science Leader

Box 13 - Broader industry engagement was ensured via a number of parallel activities, webinars, workshops and visits

| Community Webinars<br>July 2012 – Formulation SIG -<br>Launch (52 Delegates)<br>August 2012<br>Skills and Training<br>(25 delegates)<br>Sept 2012 Community updates x2<br>(22 delegates)<br>March 2012 – Story so far<br>(40 delegates)<br>Purpose:<br>• Information sharing<br>• Community building  | Open consultation<br>Questionnaire<br>Inputs received from :<br>Royal Society of Chemistry/FSTG<br>The Formulation Science and<br>Technology Group<br>IChemE Formulated Product<br>Engineering Group<br>The Academy of Pharmaceutical<br>Sciences<br>British Association for Chemical<br>Specialities<br><b>Purpose:</b><br>• Information gathering | Project-building<br>workshopsStability (Sept)<br>21 delegatesClosing the loop<br>21 delegatesSustainability<br>20 delegatesProcess<br>22 delegatesPurpose:• Stimulating<br>collaborations• Detailed technical insight |
|---|---|---|
| Company visits<br>One-on-one interviews with:<br>Representative of all major<br>sectors; includes SMEs<br>Coatings<br>Home and personal care<br>Agrichemicals<br>Ingredients<br>Drilling fluids<br>Oil additives and lubricants<br>Medicines<br>Built environment<br>Displays/electronics<br>Inks/dyes/pigments<br>Catalysts<br>Hand hygiene<br>SMEs<br><b>Purpose:</b><br>• Detailed understanding<br>of needs and limitations | connect and extended<br>KTN communityAt time of writing 204 membersDirect inputs also from:Nanotechnology KTNBiosciences KTNHealthtech and Medicines KTNPurpose:Information sharingCommunity building   |   |

Further input for the SIG was gained from events such as an APS conference session, skills webinars and events, the Chemistry Innovation Industrial Steering Board as well as Suschem UK.



# CONCLUSIONS

Formulation science and technology will assume increasing worldwide importance as a major value driver in the chemicalusing manufacturing industries. The UK has very significant strengths in industrial formulation, indeed it has the potential to be world-leading. This represents an opportunity for growth and employment via innovation and the application of formulation science and technology.

The Formulation SIG has demonstrated the need for ongoing active engagement and management of the UK's formulation community for benefit of industrial participants. This management will enable industry in the UK to realise the opportunities and meet the challenges arising from formulation and also critically enable and ensure the access to expertise and knowledge which industry needs.

Furthermore, the UK's academic community possesses very significant strengths and a depth of expertise which can support industry in formulation. However, no single institution has the full set of expertise and capabilities needed by industry. Therefore a structure involving multiple partners as envisaged in the plans for the proposed Formulation Centre will provide commercialisation opportunities for the exploitation of knowledge from academic and industrial communities.

The workshops and company consultations held by the Special Interest Group provide proof of the appetite of the UK formulation community for collaboration and for the opportunities arising from that collaboration. The Technology Strategy Board's collaborative R&D competition on formulated products will provide further ideas, innovators and partners form collaboration. The summaries of projects discussed in SIG workshops will be of value to companies seeking to build further collaborations or considering working in and with the Formulation Centre.

Finally, the Formulation SIG, the confirmed collaborative R&D funding, the proposed Formulation Centre and the planned initiatives on formulation skills development for industry together will provide the basis of a long-lasting platform for commercial and industrial success in the UK.

# RECOMMENDATIONS

1. The HVM Catapult with support from the Technology Strategy Board should implement plans to create a world class Formulation Centre to support commercialisation and innovation amongst the UK's formulating industries.

2. The Formulation Centre should be hosted by the Centre for Process Innovation as part of the HVM Catapult but it should maintain a distinct identity, branding, organisation and governance.

3. The Formulation Centre should have a hub-spoke and open access structure and be provided with the organisation and governance as outlined in this report.

4. The provisional strategic project portfolio, timescales, expertise and facilities should be taken forward during the implementation of the business plan for the Formulation Centre.

5. The strategic project portfolio described in this report should be further refined and prioritised with prospective Tier 1 member companies of the Formulation Centre and the strategic spoke organisations. This will enable collaborations to be in place ready for the start-up of the Centre.

6. The HVM Catapult and the Technology Strategy Board should ensure support and funding are available for an immediate establishment phase for the Centre. This will allow existing SIG team (companies and management team) to maintain momentum prior to handing over to Catapult management prior to April 2014.

7. The Technology Strategy Board should make plans to follow up the collaborative funding competition for formulated products (in the event that the call is heavily oversubscribed) and should ensure KTN support for development of future collaborative activities.

8. The Technology Strategy Board should work closely with EPSRC to ensure alignment of mutual strategy and portfolios in the area of formulation.

9. The Formulation Centre management and plans should ensure close collaboration of its innovation activities with the activities in skills development for formulation, such as the proposed Industrial Partnership for science-based industries.

# IMPLEMENTATION PLAN



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- British Association for Chemical Specialities
- Jenny Clucas Cogent Sector Skills Council
- Felicity Sartain Nanotechnology KTN
- Mark Bustard Healthtech and Medicines KTN
- Yvonne Armitage, David Russell, Jayne Brookman –
- Biosciences KTN
- Malcolm Hannaby Technology Strategy Board

